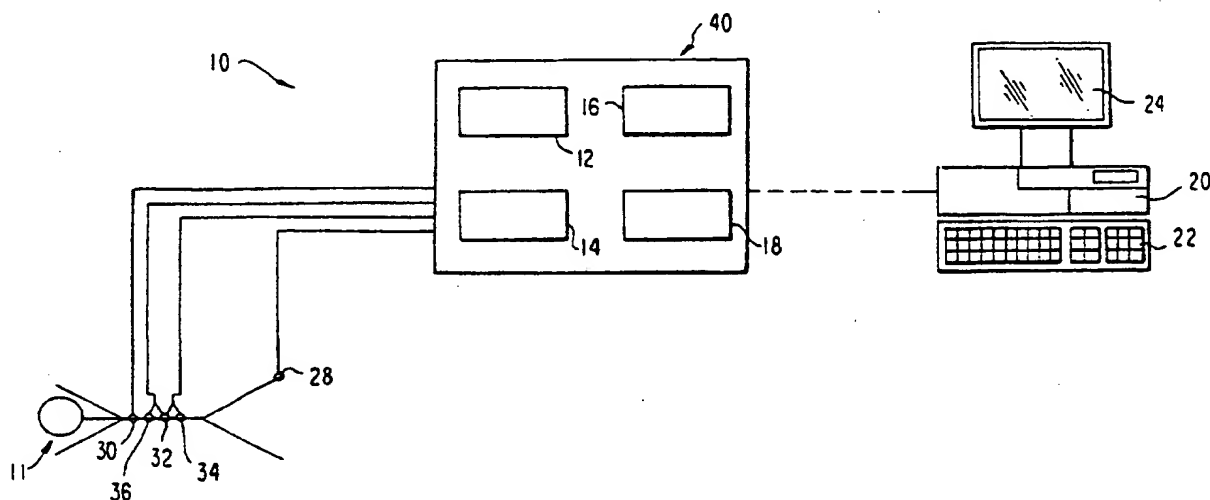




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US94/04448 <b>(22) International Filing Date:</b> 21 April 1994 (21.04.94)  <b>(30) Priority Data:</b> 08/066,593      21 May 1993 (21.05.93)      US  <b>(71) Applicant:</b> NIMS, INC. [US/US]; 1840 West Avenue, Miami Beach, FL 33140 (US).  <b>(72) Inventors:</b> SACKNER, Marvin, A.; 300 West Rivo Alto, Miami Beach, FL 33139 (US). INMAN, Dana, Michael; 759 NE 75th Street, Miami, FL 33138 (US).  <b>(74) Agent:</b> PAVANE, Martin, B.; Cohen, Pontani, Lieberman & Pavane, Suite 1210, 551 Fifth Avenue, New York, NY 10176 (US).		<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** DISCRIMINATING BETWEEN VALID AND ARTIFACTUAL PULSE WAVEFORMS



**(57) Abstract**

A method and apparatus for use in pulse oximetry for discriminating between valid pulse waveforms and artifactual pulse waveforms. Systolic upstroke times for valid pulse waveforms are in a consistent, narrow range which varies only slightly from subject to subject. This narrow range, which may be defined empirically for each subject or established by a default setting applicable to all subjects, defines a predetermined range of systolic upstroke times indicative of valid pulse waveforms. The systolic upstroke time of each pulse waveform is compared against the predetermined range, and pulse waveforms are deemed valid only if their systolic upstroke times are within the predetermined range. Only arterial oxygen saturation levels based on validated pulse waveforms are accepted. The present invention may also be used to validate the heart rate and/or R-R intervals of an ECG, and for discriminating between sleep and wakefulness in a monitored subject.

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## DISCRIMINATING BETWEEN VALID AND ARTIFACTUAL PULSE WAVEFORMS

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### BACKGROUND OF THE INVENTION

#### Field of the Invention

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This invention pertains to pulse oximetry, and more particularly to discrimination between valid and artifactual pulse waveforms obtained by pulse oximetry.

#### Prior Art

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Commercially available pulse oximeters provide instantaneous *in vivo* measurements of arterial oxygenation by determining the color of blood between a light source and a photodetector. To distinguish between the two main types of hemoglobin, i.e., oxyhemoglobin and reduced hemoglobin, measurement of light absorption is carried out at two wavelengths using a light source that consists of two different light emitting diodes, one for red and the other for infrared light. With each cardiac cycle, there is cyclic light absorption by tissue beds. During diastole, absorption is a result of venous blood, tissue, bone and pigments (melanin, nail polish, etc.). During systole, light absorption is increased by influx of arterialized blood into the tissue bed. The oximeter determines the

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and hence the pulse waveform valid when the AC/DC ratio exceeds 0.2 %, but this standard has not been validated. At least one manufacturer of pulse oximeters employs an autogain program to flesh out low amplitude pulse waveforms for display when the AC/DC ratio falls below 0.2 %. However, arterial oxygen saturation values at signal strengths below this threshold may still be valid provided the pulse waveform has a normal configuration. See, e.g. Wukitsch, et al., *Pulse Oximetry: Analysis of Theory, Technology, and Practice*, J. Clin. Monit. 1988; 4: 290-301.

At least one manufacturer of pulse oximeters has approached the motion artifact problem by synchronizing data acquisition by the pulse oximeter with the R wave of an ECG. However, the oximeter may synchronize with ECG artifacts caused by motion or shivering, resulting in erroneous readings. Furthermore, with this approach the pulse rate displayed by the oximeter is necessarily equal to the heart rate derived from the ECG, thereby eliminating concordance of pulse oximeter pulse rate with ECG heart rate as a validator of pulse oximetry data. See Alexander, et al., *Principles of Pulse Oximetry: Theoretical and Practical Considerations*. Anesth. Analg. 1989; 68: 368-376. This technique may also be subject to error because of the variability in operator and/or computer selection of peak to peak and trough to trough points of the pulse waveform, as well as inherent errors related to sampling rates, all of which affect the calculation of arterial saturation values.

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monitoring long term trends, as in critically ill patients.

It is accordingly an object of the present invention to provide a method and apparatus for validating arterial oxygen saturation measurements obtained with pulse oximetry.

5 It is another object of the invention to provide a method and apparatus for verifying arterial oxygen saturation measurements derived from pulse oximetry by verifying the validity of the pulse waveforms detected by a pulse oximetry sensor.

10 It is a further object of the present invention to provide a method and apparatus of the aforementioned type which discriminates between valid and invalid pulse waveforms on a real time basis.

15 It is yet a further object of the present invention to provide a method and apparatus of the aforementioned type which is highly accurate in its discrimination between valid and invalid pulse waveforms, even in the case of low amplitude pulse waveforms.

### SUMMARY OF THE INVENTION

20 The method and apparatus of the present invention verifies the validity of pulse waveforms obtained with pulse oximetry by detecting the systolic upstroke time for each pulse waveform, i.e. the time from onset of systole to peak, comparing the detected systolic upstroke time to

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oximeter or to the digital computer itself. Then, as new pulse waveforms are collected from the pulse oximeter, their systolic upstroke times are compared with the predetermined range of acceptable values, and arterial oxygen saturation values are displayed and/or stored only if the systolic upstroke time of the respective pulse waveform falls within the predetermined range.

Pulse waveforms for which the systolic upstroke time falls outside of the predetermined range are considered distorted by motion artifact and the corresponding arterial oxygen saturation levels are rejected. Since it is accepted that skeletal muscles are inactive during sleep, the rejected waveforms indicative of motion artifact may be used to distinguish wakefulness from sleep in a manner analogous to actigraphs.

Broadly speaking, the present invention is a method for detecting artifactual pulse waveforms in pulse oximetry comprising measuring one of the systolic upstroke time and the diastolic time of pulse waveforms generated by a pulse oximeter monitoring a subject, comparing the selected one of the measured systolic upstroke time and diastolic time to a predetermined range of systolic upstroke times and diastolic times, respectively, indicative of a correct pulse waveform, and rejecting as artifactual pulse waveforms wherein the selected one of the measured systolic upstroke time and the diastolic time is outside its respective predetermined range. Preferably, the selected one of the systolic upstroke

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for determining the pulse rate of the pulse waveforms generated by the pulse oximeter, and means for indicating that the pulse rate of non-rejected pulse waveforms is approximately equal to the heart rate.

5 These as well as further features and advantages of the present invention will be more fully apparent from the following detailed description and annexed drawings of a presently preferred embodiment thereof.

#### **BRIEF DESCRIPTION OF THE DRAWING**

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In the drawings:

Fig. 1 is a diagrammatic representation of an apparatus in accordance with the present invention; and

15 Figs. 2-13 are polygraphic recordings illustrating the methodology of the present invention.

#### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

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Referring now to the drawings, and initially to Fig. 1 thereof, an apparatus in accordance with the present invention is generally designated at 10. As noted above and explained more fully below, the primary purpose of the present invention is to confirm the validity of

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in each of Figs. 2-13. In accordance with the apparatus 10 shown in Fig. 1, the data from the Respitrace PT is downloaded to a removable hard drive which is then transferred to the computer 20 for generating hard copy recordings on the device 26. As will become more fully apparent as this description progresses, the apparatus 10 and the waveforms depicted in Figs. 2-13 serve primarily to validate the methodology of the present invention. In actual use of the invention, therefore, the apparatus 10 may be substantially simplified, as more fully explained below.

In the waveforms of Figs. 2-13, the abscissa depicts the time lapse in seconds or minutes. The 12 depicted waveforms in each of Figs. 2-13 have the following significance: (1) ECG is the output waveform of the electrocardiogram 14; (2) R-R represents the interval between successive R-wave peaks as detected as by the R-wave trigger of the ECG, with the amplitude of the spikes denoting the R-R interval in milliseconds; (3) HR is the heart rate in beats per minute as computed from the R-R intervals of the ECG; (4) PR is the pulse rate as detected from the pulse waveform output from the pulse oximeter 12, also given in beats per minute; (5) OxiP is the analog representation of the pulse waveform output from the pulse oximeter 12, with the ordinate denoting amplitude in arbitrary units; (6) Sy is the systolic upstroke time of the pulse waveform OxiP, i.e. the time interval from the onset of systolic upstroke to peak systolic upstroke as derived from the OxiP waveform and shown, by way

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by the RespiEvents program from the pulse waveform OxiP transmitted to the Respitrace PT from the sensor 28. Referring to Fig. 2, which is a time plot of about 8.5 seconds duration, the systolic upstroke time Sy is displayed as a continuous waveform and, as noted earlier, represents the time interval between the onset of systole and peak, shown by way of example as  $\Delta t$  on the seventh pulse waveform OxiP in Fig. 2. The artifact in the leftmost portion of the Sy tracing in Fig. 2 is an initialization artifact. After this artifact, it may be seen that the systolic upstroke time Sy is relatively stable from pulse to pulse, generally in the range of 0.1 to 0.2 seconds. Since, following the initialization artifact, the detected values of Sy are within the predetermined range, each pulse in the OxiP waveform is deemed correct, i.e. unaffected by motion artifacts or other distortions. Consequently, each pulse following the initialization artifact receives a binary logic 1 in the PG tracing, which provides a visual indication as to whether each pulse waveform is good (logic 1) or bad (logic 0).

As noted above, the predetermined range of systolic upstroke times used for comparison with detected systolic upstroke times for validating pulse waveforms can be empirically derived on a single subject. Alternatively, considering that empirical observation confirms that systolic upstroke times are in a consistently narrow range from subject to subject, including infants, children and adults, a default range may be incorporated in the software thereby avoiding the necessity for establishing a range for



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Fig. 3 is a tracing similar to Fig. 2, and illustrating both valid and invalid pulse waveforms (OxiP). During the period when the pulse waveforms appear normal, the systolic upstroke time  $S_y$  is within the acceptable range, and the resulting pulses are deemed valid, as evidenced by the logic 1 pulses on the PG waveform. However, during periods when the pulse waveform OxiP is abnormal, the systolic upstroke time  $S_y$  is outside of the acceptable range, and the corresponding pulses are deemed not valid, as represented by a logic 0 on the PG waveform. Again, during periods when the pulses are rejected as confirmed by the PG tracing, the corresponding arterial oxygen saturation levels are likewise rejected as invalid. Fig. 3 covers a time duration of about 50.1 seconds.

Fig. 4 is another waveform similar to Fig. 2, and covering a time duration of about 80.5 seconds. Fig. 4 is significant primarily for the leftmost portion of the tracing, wherein it may be seen that the reduced amplitude of the ECG resulted in incorrect R-R intervals and heart rate HR due to the failure of the R-wave trigger on two different heart beats. In contrast, during these heart beats, the systolic upstroke times ( $S_y$ ) of the corresponding pulses on the OxiP waveform were within the predetermined range resulting in classification of these pulses as "good" ( $PG=1$ ) and validation of the corresponding  $SaO_2$  measurements. The pulse rate PR derived from these pulses is, therefore, also correct.

Fig. 5 is another tracing similar to Fig. 2, and covering a

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apparatus of the present invention for discriminating acceptable pulse waveforms (OxiP) based on systolic upstroke time permits valid arterial oxygen saturation measurements during the brief periods when the pulse oximeter sensor is stable and the systolic upstroke times are within the predetermined range as indicated, for example, by the notation "VALID" approximately in the middle of the plot of Fig. 7.

Fig. 7 also illustrates the validity of utilizing systolic upstroke times outside the predetermined range for discriminating sleep from wakefulness. Note that during periods of wakefulness, as confirmed by body movements evident from the wide band oscillations on the Vt and Imp waveforms, the systolic upstroke times Sy are also outside the predetermined range. Conversely, when the body portion to which the pulse oximeter sensor is attached is stable, indicating sleep, the systolic upstroke time is within the predetermined range. Therefore, rejected systolic upstroke times Sy, i.e. systolic upstroke times outside the predetermined range, may be relied upon alone, or in conjunction with other sensors, for discriminating wakefulness from sleep, similar to an actigraph.

Fig. 8 is another waveform similar to Fig. 2, covering a period of about 8.7 seconds. Fig 8. is included simply to illustrate that the pulse oximeter waveform OxiP is approximately one beat behind the ECG waveform owing to electronic filtering of the pulse oximeter waveform

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movement. Consequently, a determination as to whether the subject is asleep or awake is inconclusive, and for purposes of analysis it may be assumed that the subject is sleeping. On the second part of the tracing, in the area marked "awake" at the 7-8 minute mark, wakefulness is confirmed by all three of the Mvmnt, Vt and Imp tracings, each of which suggests patient movement. Accordingly, the subject is confirmed as awake during this interval.

Apart from validating arterial oxygen saturation measurements and discriminating between wakefulness and sleep, another application of the method and apparatus of the present invention is for validating R-R intervals or heart rate (HR) as derived from the ECG output. R-R intervals are a useful analytical tool. For example, it has been observed that R-R intervals become quite regular prior to a loss of autonomic nervous system function that may signal the possibility of sudden cardiac death. For long term collection of R-R intervals, typically full ECG waveforms are not collected, but rather only the numerical values of the R-R time intervals are recorded to minimize storage space as on a disk, tape drive, etc. For this application, it is known to edit the recorded data for artifacts, typically caused by motion, using statistically based filters, as such artifacts render the corresponding R-R intervals unreliable. See, for example, Malik, *Heart Rate Variability in Relation to Prognosis After Myocardial Infarction: Selection of Optimal Processing Techniques*,

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stored, in which event the pulse oximeter or related equipment may be equipped with warnings and/or alarms based on the trend of validated R-R intervals, e.g. if the R-R intervals become regular or indicate bradycardia or tachycardia.

5                   In accordance with the present invention, R-R intervals can be validated as follows: (1) if the pulse rate (PR) as derived from the OxiP waveform is close to the heart rate (HR) measured with an ECG and the systolic upstroke times (Sy) of the OxiP waveforms are within the predetermined range, then the corresponding R-R intervals are deemed  
10                   valid; (2) if the pulse rate (PR) derived from the OxiP waveform markedly differs from the heart rate (HR), and the corresponding systolic upstroke times (Sy) fall outside of the predetermined range, the validity of the R-R intervals is uncertain, as it is possible that the pulse rate (PR) results from movement artifacts, in which event the R-R intervals could be valid, though  
15                   it is also possible that the R-R intervals are invalid as there is no independent confirmation; (3) if the pulse rate (PR) derived from the OxiP waveform is close to the heart rate (HR) from the ECG but the systolic upstroke times (Sy) are outside the valid range, then again the R-R intervals cannot be considered validated, since the validity of the OxiP  
20                   pulse waveform is not validated by the systolic upstroke time (Sy), and hence the comparison between the pulse rate (PR) derived from the OxiP waveform and the heart rate (HR) cannot be presumed valid; and (4) if the

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i.e. a slowing of the heart rate. In Fig. 11, the bradycardia is noted by a "B" on the HR tracing at approximately the 6:20 marker. The bradycardia is considered confirmed since during the bradycardia the systolic upstroke times (Sy) measured from the pulse oximeter waveform (OxiP) are within the predetermined range as confirmed by the logic 1 pulses on the PG tracing. Furthermore, the pulse rate (PR) of the OxiP pulse waveform as shown on the PR tracing is approximately the same as the heart rate (HR) derived from the ECG and shown on the HR tracing. The periods of tachycardia marked by a "T" on the HR tracing are not considered confirmed, since many of the rapid beats were recorded during periods when the pulse oximeter waveform OxiP was deemed unacceptable based on its systolic upstroke times, as confirmed by the logic 0 pulses on the PG waveform. In other words, the pulse oximetry data cannot be deemed reliable during these intervals and hence cannot validate the heart rate as derived from the ECG.

Fig. 12 is another waveform similar to Fig. 2 showing a time plot having a duration of about 40 seconds. Fig. 12 demonstrates use of the method and apparatus of the present invention to verify cardiac arrhythmia as derived from the ECG. In Fig. 12, the ECG recording suggests a bradycardia. However, during the same interval, the pulse waveforms derived from the pulse oximeter (OxiP) are mostly normal, as suggested by the logic 1 pulses on the PG waveform. This suggests that

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(PR) as derived from the Oxip waveform differs markedly from the reduced heart rate (HR) detected by the ECG, and the OxiP waveform is deemed valid during this interval as confirmed by the logic 1 pulses on the PG waveform.

5                   Thus far, and as is preferred, the pulse waveform (OxiP) generated by the pulse oximeter is validated with reference to the systolic upstroke time (Sy). Alternatively, the diastolic time of the pulse waveforms may be utilized. However, this is not preferred because while diastolic times are reliable in subjects with regular cardiac rhythms, they  
10                   become variable in the presence of cardiac arrhythmia.

                  As noted hereinabove, the apparatus 10 depicted in Fig. 1 was intended primarily for verifying the methodology of the present invention though, of course, it can also be used for practicing the invention. Where the invention is used simply as a validator of pulse  
15                   oximetry data, much of the apparatus shown in Fig. 1 can be dispensed with. In particular, it is contemplated that the invention may be used with a conventional pulse oximeter modified to incorporate the teachings of the present invention. In this regard, it is well within the capabilities of a  
20                   person of ordinary skill in the art who has read this description to modify a conventional pulse oximeter to calculate the systolic upstroke time of the pulse waveform and compare that systolic upstroke time, as on a pulse by pulse basis, with a predetermined range. It is similarly within the

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examples described are for illustrative purposes only and are not to be construed as limiting the scope of the present invention which is properly delineated only in the appended claims.

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3. The method of claim 1, further comprising the steps of first determining one of the systolic upstroke times and diastolic times for a plurality of pulse waveforms for said subject; and

determining said predetermined range from said  
5 selected one of said systolic upstroke times and said diastolic times for said plurality of pulse waveforms.

4. The method of claim 3, further comprising the step of verifying that the waveforms of said plurality of pulse waveforms are normal.

10 5. The method of claim 3, wherein said step of determining said predetermined range of one of said systolic upstroke times and diastolic times comprises determining one of the mean and median of the selected one of said systolic upstroke times and diastolic times for said plurality of pulses; and

15 establishing said predetermined range as within a predetermined time interval having a minimum less than one of said mean and median and a maximum greater than one of said mean and median.

6. The method of claim 2, wherein said predetermined range is from about .09 seconds to about .21 seconds.

20 7. The method of claim 1, wherein said pulse oximeter outputs a signal indicative of the arterial oxygen saturation level of said subject, and further comprising the step of rejecting arterial oxygen saturation levels based on data generated during a time period corresponding to a rejected pulse waveform.

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of storing data corresponding to the heart rate when the heart rate is validated.

15. The method of claim 12, wherein said step of validating the subject's heart rate comprises validating the subject's R-R intervals.

16. An apparatus for detecting artifactual pulse waveforms in pulse oximetry comprising:

means for measuring one of the systolic upstroke time and the diastolic time of pulse waveforms generated by a pulse oximeter monitoring a subject;

means for comparing the selected one of the measured systolic upstroke time and diastolic time to a predetermined range of systolic upstroke times and diastolic times, respectively, indicative of a correct pulse waveform; and

means for rejecting as artifactual pulse waveforms wherein the selected one of the measured systolic upstroke time and the diastolic time is outside its respective predetermined range.

17. The apparatus of claim 16, wherein said means for measuring comprises means for measuring the systolic upstroke times of pulse waveforms generated by a pulse oximeter monitoring a subject;

wherein said means for comparing comprises means for comparing the measured systolic upstroke times to a predetermined range of systolic upstroke times; and

wherein said means for rejecting comprises means for

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of said subject, and further comprising means for rejecting arterial oxygen saturation levels based on data generated during a time period corresponding to a rejected pulse waveform.

5           23.    The apparatus of claim 22, wherein said means for rejecting said arterial oxygen saturation levels comprises means for rejecting said arterial oxygen saturation levels on a real time basis.

          24.    The apparatus of claim 23, further comprising means for storing the non-rejected arterial oxygen saturation levels.

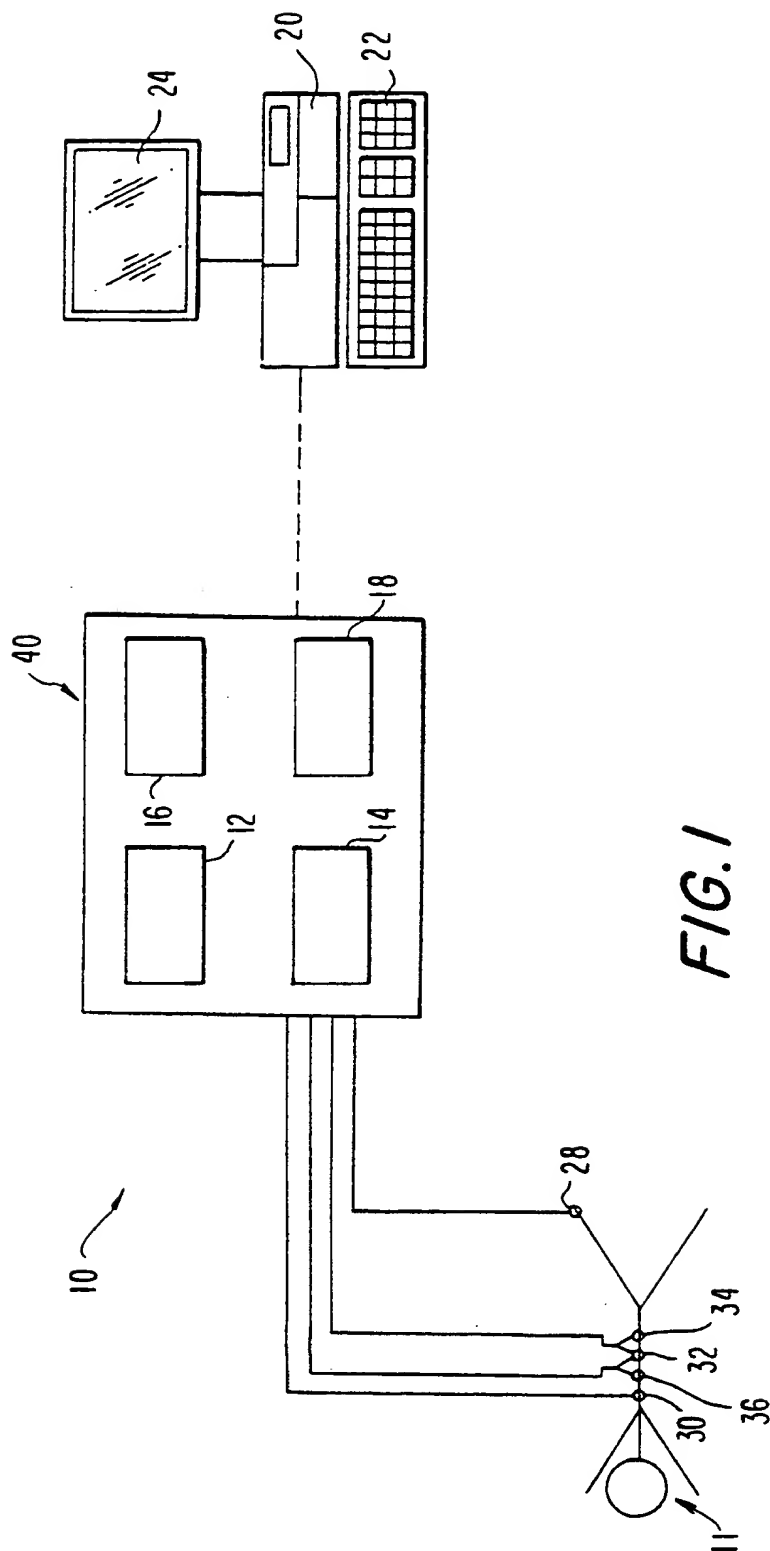
10           25.    The apparatus of claim 16, further comprising means for classifying said subject as awake during time intervals corresponding to rejected pulse waveforms and as asleep during time intervals corresponding to non-rejected pulse waveforms.

15           26.    The apparatus of claim 25, further comprising means for monitoring said subject's breathing and wherein said means for classifying comprises means for classifying said subject as awake only when said rejected pulse waveforms persist for at least about one breath.

20           27.    The apparatus of claim 16, further comprising an ECG for generating a signal indicative of the subject's heart rate; means for determining the pulse rate of the pulse waveforms generated by the pulse oximeter; and means for indicating that the pulse rate of non-rejected pulse waveforms is approximately equal to the heart rate.

          28.    The apparatus of claim 26, wherein said indicating means comprises means for indicating on a real time basis that the pulse rate of non-rejected pulse waveforms is approximately equal to the heart

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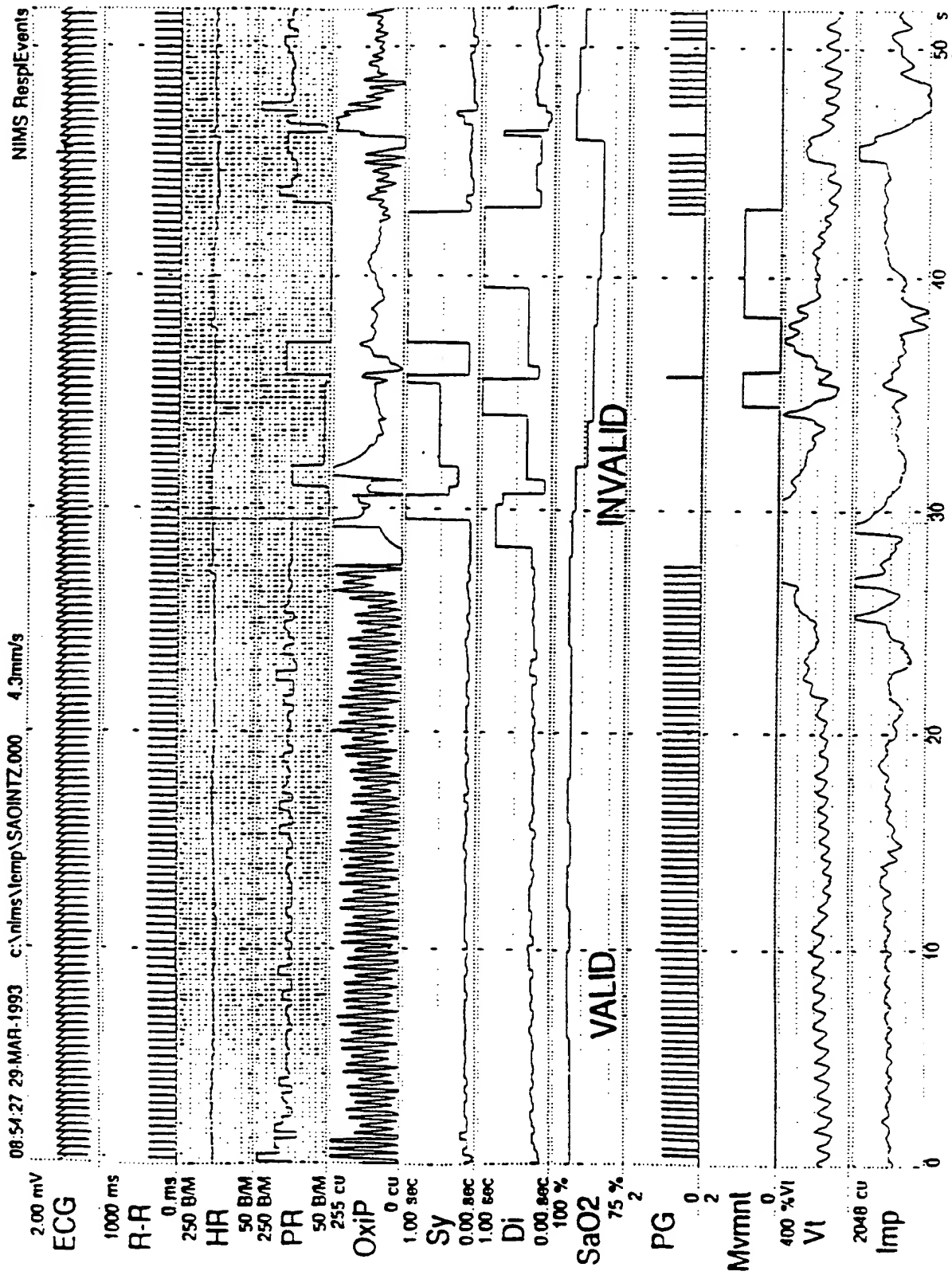


FIG. 3

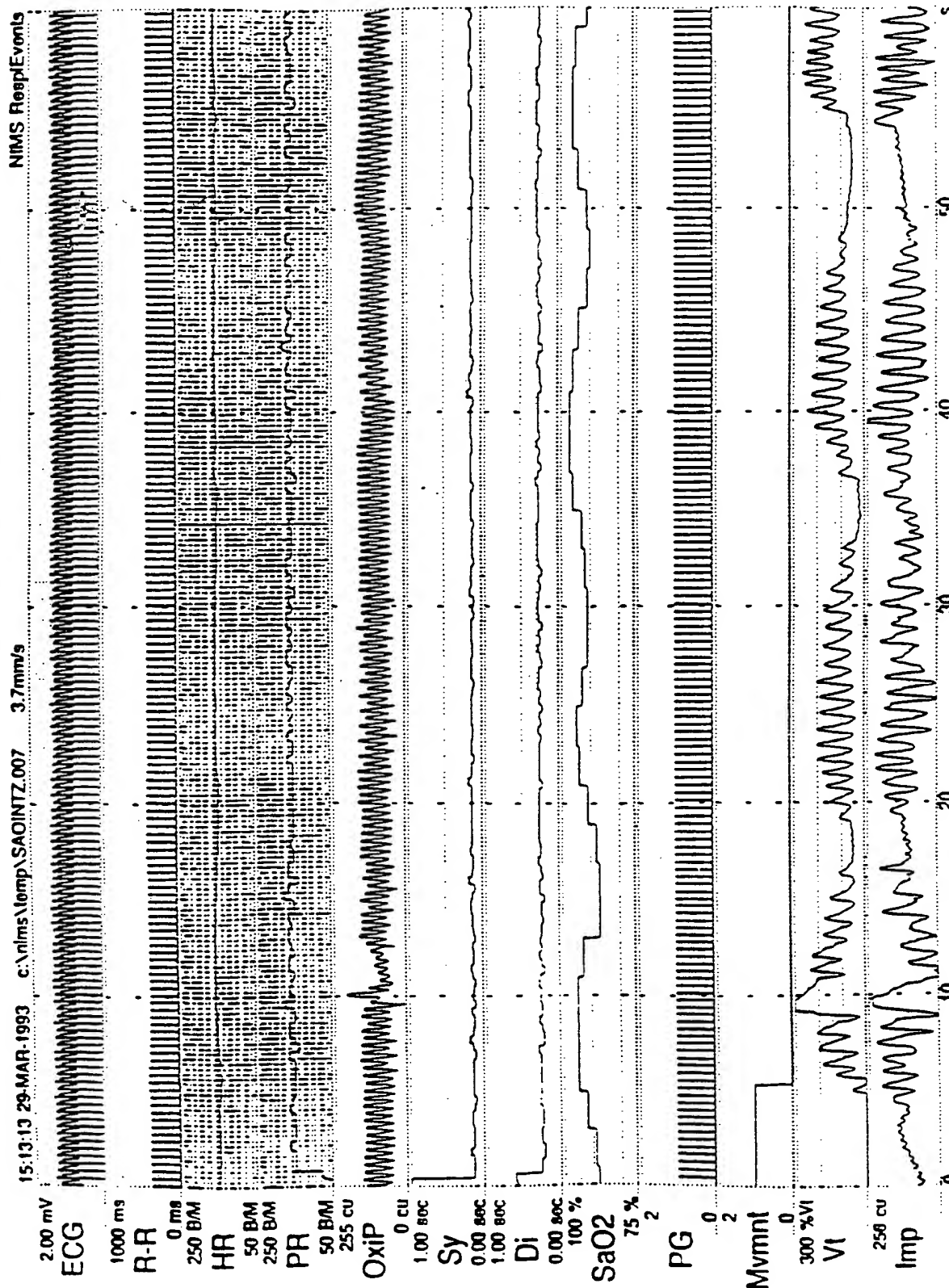


FIG. 5

NORMAL OXIP IN PRESENCE OF PERIODIC BREATHING

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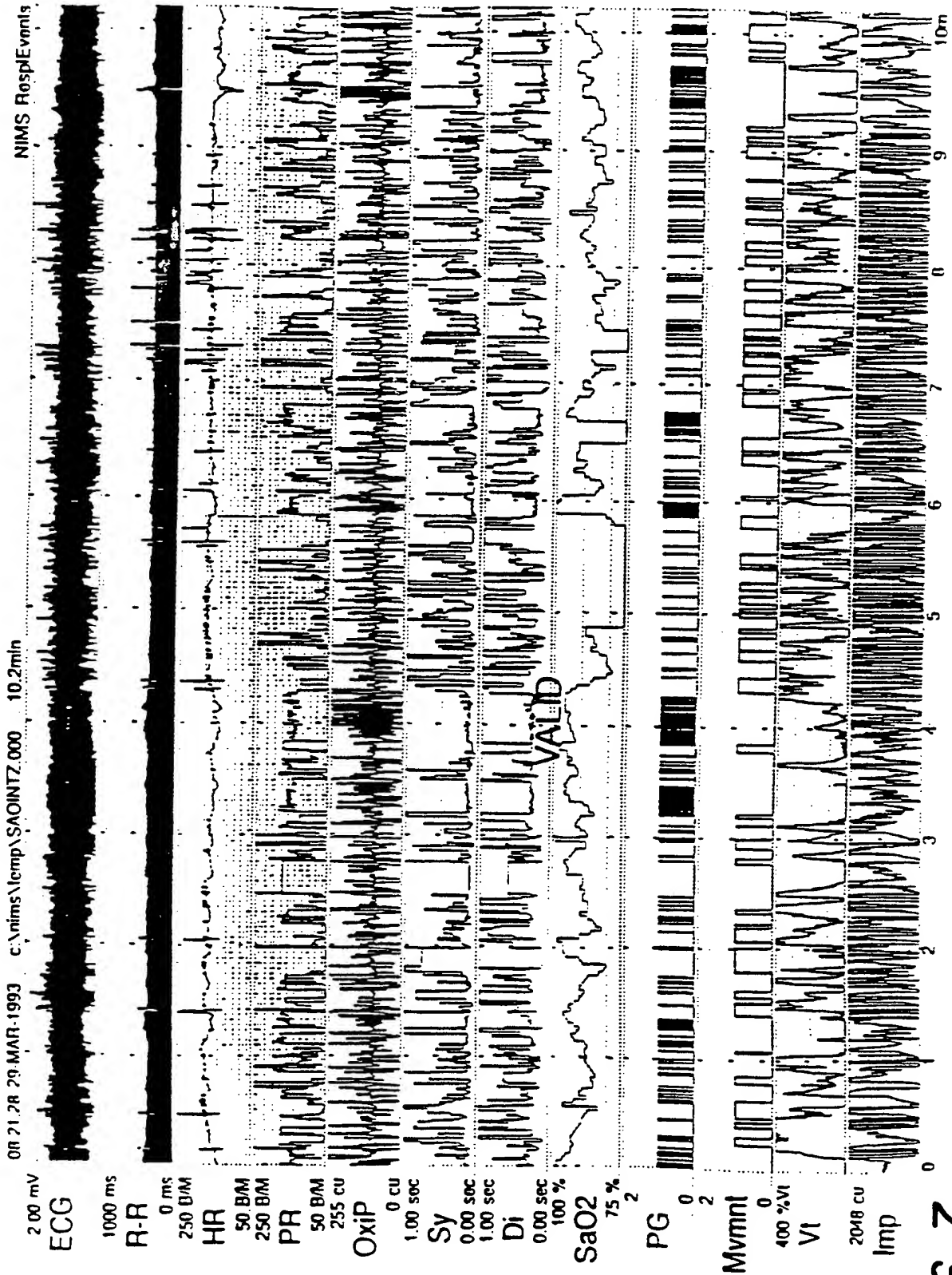
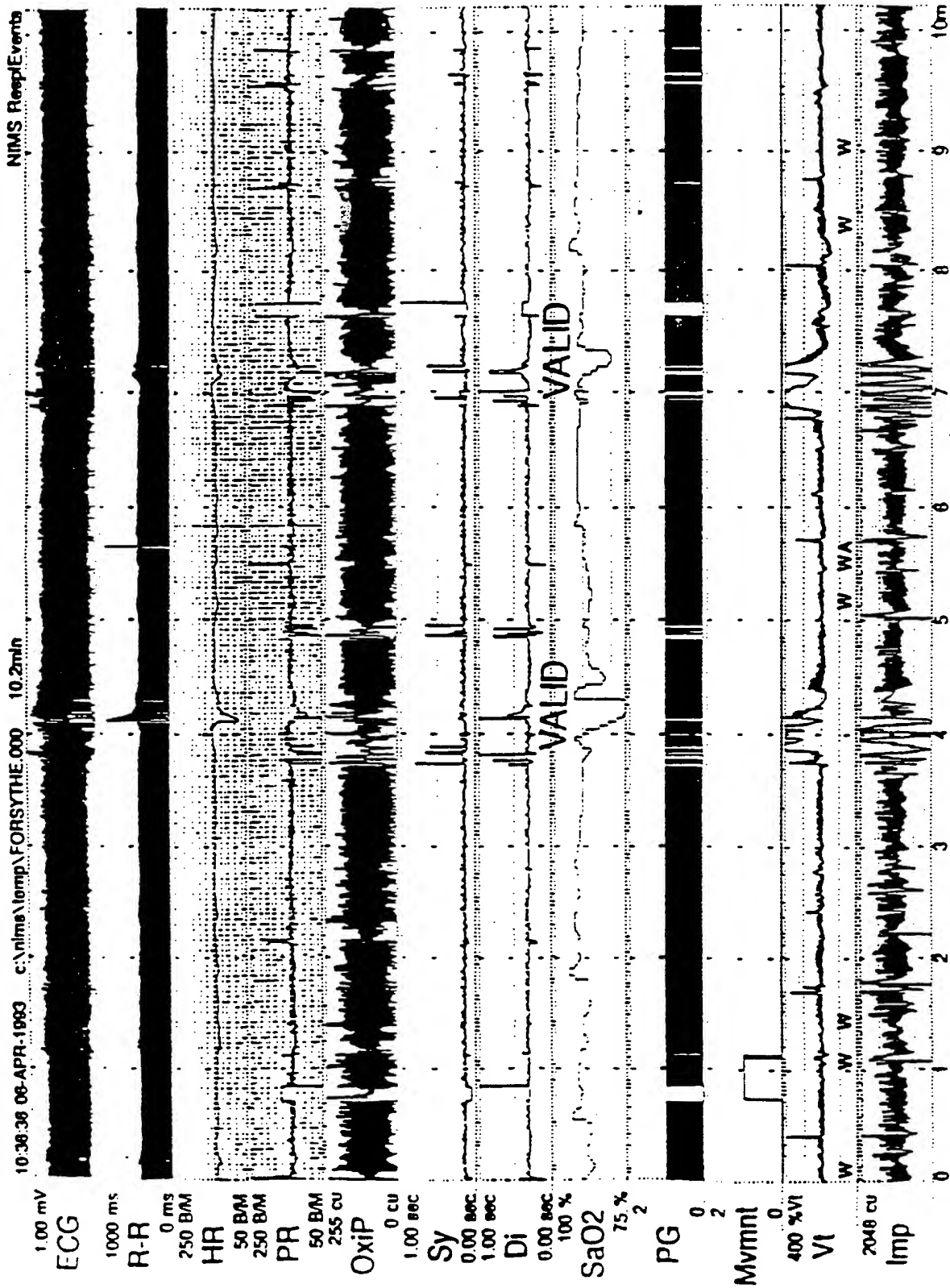
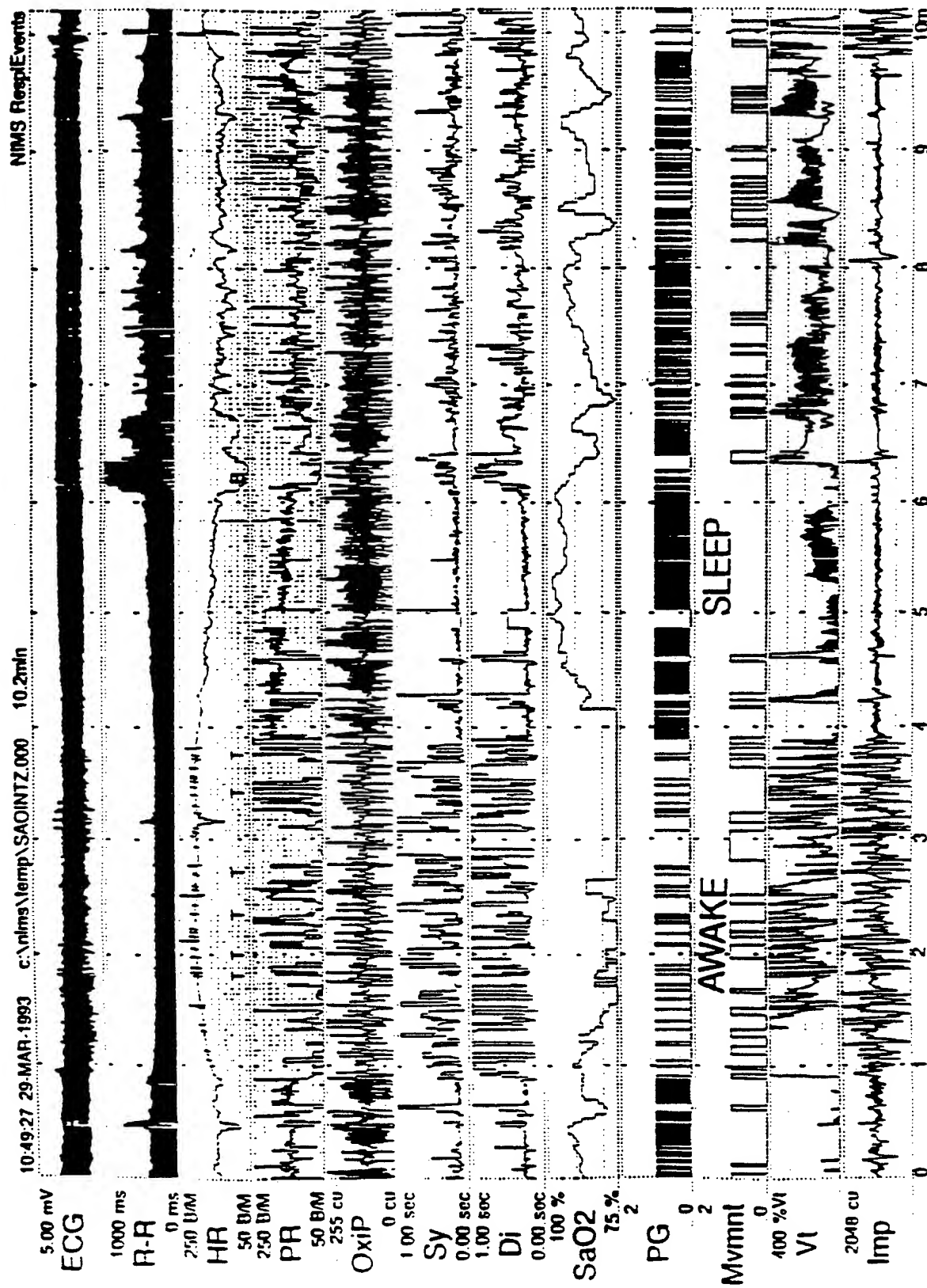


FIG. 7 VALIDITY OF O2 SAT WITH MARKED BODY MOVEMENTS (VT & IMP)

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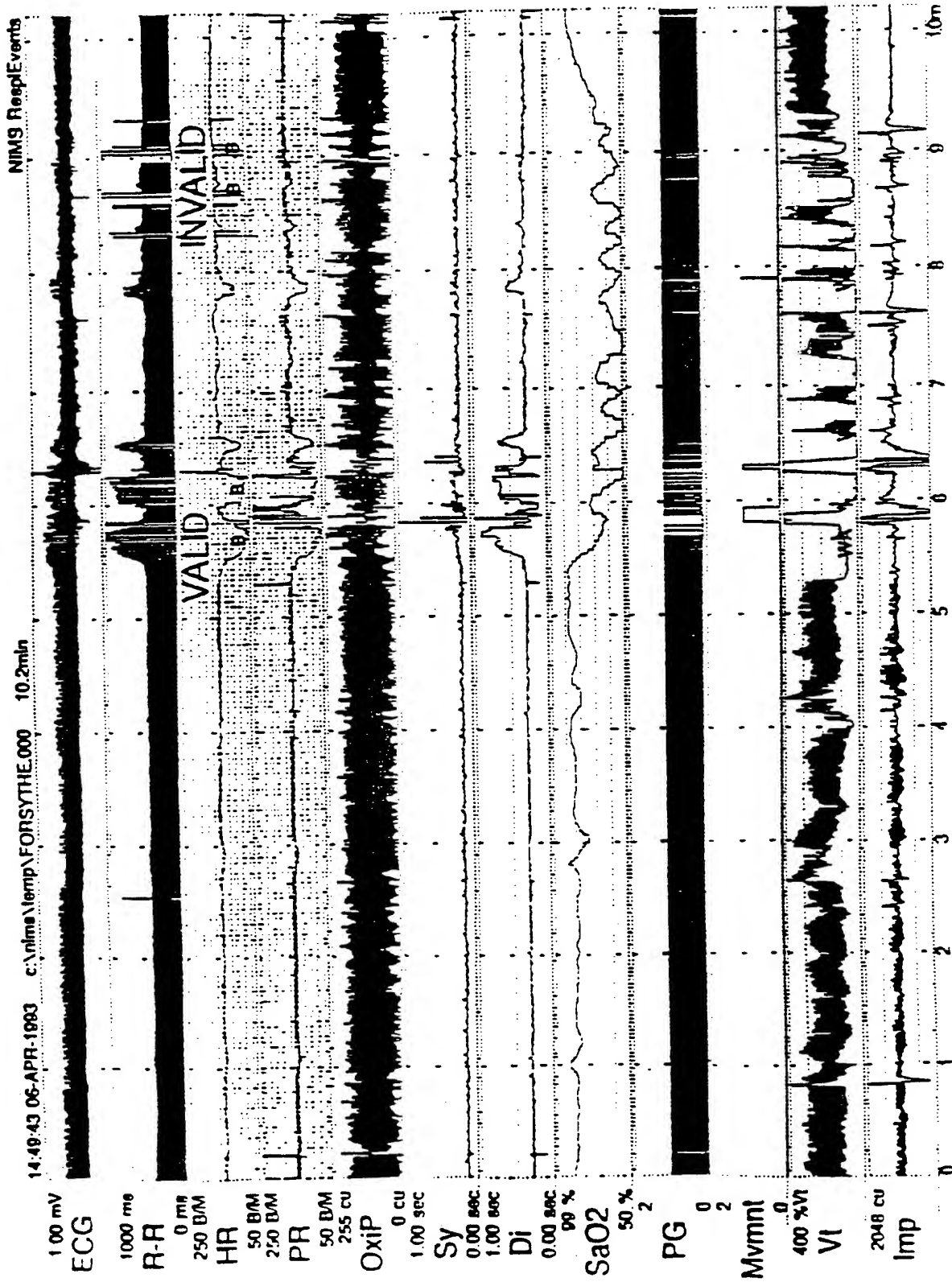


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TRUE BRADYCARDIA (B); EQUIVOCAL TACHCARDIA (T) *FIG. 11*



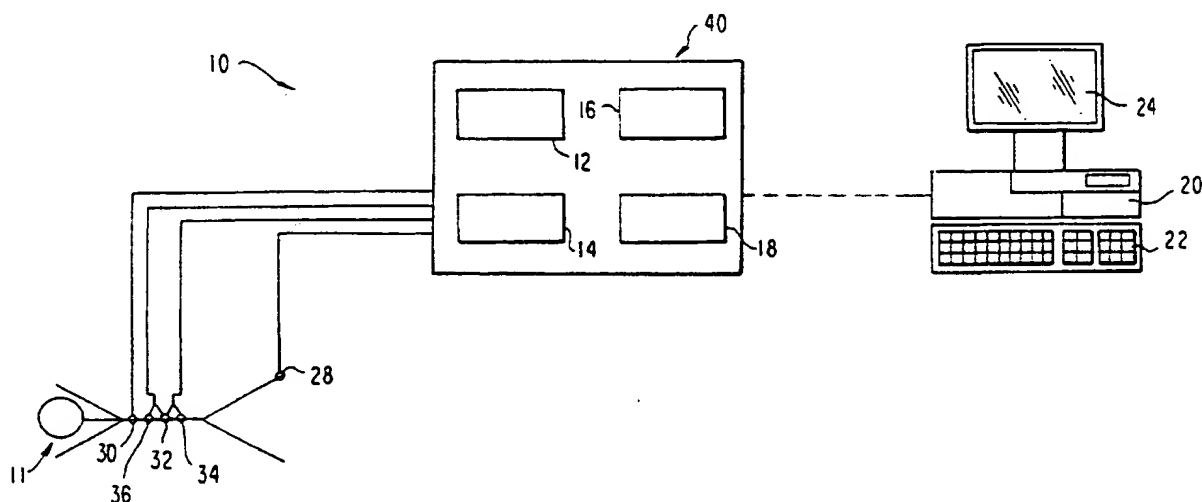


TRUE & FALSE BRADYCARDIA (B) FIG. 13



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US94/04448 <b>(22) International Filing Date:</b> 21 April 1994 (21.04.94)  <b>(30) Priority Data:</b> 08/066,593      21 May 1993 (21.05.93)      US  <b>(71) Applicant:</b> NIMS, INC. [US/US]; 1840 West Avenue, Miami Beach, FL 33140 (US).  <b>(72) Inventors:</b> SACKNER, Marvin, A.; 300 West Rivo Alto, Miami Beach, FL 33139 (US). INMAN, Dana, Michael; 759 NE 75th Street, Miami, FL 33138 (US).  <b>(74) Agent:</b> PAVANE, Martin, B.; Cohen, Pontani, Lieberman & Pavane, Suite 1210, 551 Fifth Avenue, New York, NY 10176 (US).		<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published <i>With international search report.</i> <i>With amended claims.</i>  <b>Date of publication of the amended claims:</b> 16 February 1995 (16.02.95)

**(54) Title:** DISCRIMINATING BETWEEN VALID AND ARTIFACTUAL PULSE WAVEFORMS**(57) Abstract**

A method and apparatus for use in pulse oximetry for discriminating between valid pulse waveforms and artifactual pulse waveforms. Systolic upstroke times for valid pulse waveforms are in a consistent, narrow range which varies only slightly from subject to subject. This narrow range, which may be defined empirically for each subject or established by a default setting applicable to all subjects, defines a predetermined range of systolic upstroke times indicative of valid pulse waveforms. The systolic upstroke time of each pulse waveform is compared against the predetermined range, and pulse waveforms are deemed valid only if their systolic upstroke times are within the predetermined range. Only arterial oxygen saturation levels based on validated pulse waveforms are accepted. The present invention may also be used to validate the heart rate and/or R-R intervals of an ECG, and for discriminating between sleep and wakefulness in a monitored subject.

**AMENDED CLAIMS**

[received by the International Bureau on 12 December 1994 (12.12.94);  
original claims 1-29 amended; new claims 30 and 31 added (8 pages)]

1. A method for discriminating between artifactual pulse waveforms and pulse waveforms indicative of arterial oxygen saturation levels of a subject comprising:

receiving pulse waveforms, at least some of the received pulse waveforms being indicative of arterial oxygen saturation levels of a subject;

measuring one of a first parameter selected from the group of systolic upstroke times and diastolic times for pulse waveforms received during said receiving step;

comparing the measured first parameter to a predetermined range of the first parameter indicative of a correct pulse waveform;

rejecting as artifactual any of the pulse waveforms corresponding to a measured first parameter outside the predetermined range of the first parameter.

2. The method of claim 1, wherein said measuring step comprises measuring the systolic upstroke times of the received pulse waveforms;

wherein said comparing step comprises comparing the measured systolic upstroke times to a predetermined range of systolic upstroke times; and

wherein said rejecting step comprises rejecting as artifactual any of the pulse waveforms wherein the respective one of the measured systolic upstroke times is outside said predetermined range of systolic upstroke times.

**AMENDED SHEET (ARTICLE 19)**

7. The method of claim 1, wherein said received pulse waveforms correspond to signals output by a pulse oximeter, said method further comprising rejecting arterial oxygen saturation levels of the subject based on data generated from said signals, during time periods respectively corresponding to rejected pulse waveforms.

8. The method of claim 7, wherein said step of rejecting said arterial oxygen saturation levels comprises rejecting said arterial oxygen saturation levels on a real time basis.

9. The method of claim 8, further comprising the step of storing arterial oxygen saturation levels based on data generated during times other than those respectively corresponding to rejected pulse waveforms.

10. The method of claim 1, further comprising the step of determining whether said subject is asleep or awake by classifying said subject as awake during first time intervals corresponding to rejected pulse waveforms and as asleep during second time intervals corresponding to non-rejected pulse waveforms.

11. The method of claim 10, further comprising the step of monitoring said subject's breathing and wherein said classifying step comprises classifying said subject as awake only when said rejected pulse waveforms persist for at least about one breath.

means for rejecting as artifactual any of the pulse waveforms corresponding to a measured first parameter outside the predetermined range of the first parameter.

17. The apparatus of claim 16, wherein said means for measuring is operative to measure systolic upstroke times of the received pulse waveforms;

wherein said means for comparing is operative to compare measured systolic upstroke times to the predetermined range of systolic upstroke times; and

wherein said means for rejecting is operative to reject as artifactual any of the pulse waveforms wherein the respective one of the measured systolic upstroke times is outside said predetermined range of systolic upstroke times.

18. The apparatus of claim 16, comprising means for performing a second measuring step wherein the first parameter selected from the group of the systolic upstroke times and diastolic times is measured for a plurality of pulse waveforms generated by the pulse oximeter for said subject prior to said first measuring step; and further comprising

means for determining said predetermined range from said selected first parameter measured during said second measuring step.

19. The apparatus of claim 18, further comprising means for verifying that said plurality of pulse waveforms of said second measuring step have normal waveforms.

25. The apparatus of claim 16, further comprising means for classifying said subject as awake during first time intervals corresponding to rejected pulse waveforms and as asleep during second time intervals corresponding to non-rejected pulse waveforms.

26. The apparatus of claim 25, further comprising means for monitoring said subject's breathing and wherein said means for classifying is operative to clarify said subject as awake only when said rejected pulse waveforms persist for at least about one breath.

27. The apparatus of claim 16, further comprising an ECG for generating a signal indicative of a heart rate of the subject; means for determining a pulse rate of the pulse waveforms generated by the pulse oximeter; and means for indicating that the pulse rate of non-rejected pulse waveforms is approximately equal to the heart rate.

28. The apparatus of claim 27, wherein said indicating means is operative to indicate, on a real time basis, that the pulse rate of non-rejected pulse waveforms is approximately equal to the heart rate.

29. The apparatus of claim 28, further comprising means for storing data corresponding to the heart rate when the heart rate is approximately equal to the pulse rate.